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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,940	01/21/2004	Gyorgy Domany	1000546-0003	4047

7590 06/07/2007
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EXAMINER

CHANG, CELIA C

ART UNIT	PAPER NUMBER
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1625

MAIL DATE	DELIVERY MODE
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06/07/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/761,940	Applicant(s) DOMANY ET AL.	
	Examiner Celia Chang	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-8,10,11 and 13-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-8,10,11,16-37 and 1314 is/are rejected.
- 7) ☒ Claim(s) 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Amendment and response filed by applicants dated Mar. 23, 2007 have been entered and considered carefully.

Claims 5, 9, 12 have been canceled. Claim 38 and the remaining subject matter of claims 1-4, 6-8, 10-14, 16-37 are withdrawn from consideration.

Claims 1-4, 6-8, 10-11, 13-37 reading on claim 15 are prosecuted.

Please note that the election of group I is $m+n$ is four i.e. piperidiny compounds. The amended claims have not been limited to this subject matter.

2. The rejection of claims 1-4, 6-7, 10, 13, 16-37 under 35 USC 112 first paragraph for lacking enablement for the unlimited scope of all heterocyclic rings encompassed by the claims is maintained for reason of record.

Applicants submitted no rebuttal for the rejection. While description and starting material can be found for the scope of claims 8, 11, and 14, the description and starting material for claims 1-4, 6-7, 10, 13, 16-37 are lacking. Not only description and starting material for the compounds of such breadth of heterocyclic ring encompassed by claims 1-4, 6-7, 10, 13, 16-37 are lacking, there is insufficient evidence that in such complex and highly unpredictable art that all compounds of such breadth can have the same utility. In addition, the lack of description for the breadth is further supported by the difference between the instantly amended claims and the priority documents wherein support is limited to the scope of claims 8, 11 and 14.

3. The rejection of claims 1-4, 6-8, 10-11, 13-14, 16-28 and 37 under 35 USC 112 first paragraph for lacking sufficient support as to enable one skilled in the art to which it pertains as to how to use the compounds is maintained for reason of record.

A detailed analysis of the state of the art, the scope of the claims and the descriptive and enabling support of the specification was made in the previous office action. It was observed that the specification disclosed myriads of compounds with an enormous variation of symptoms, conditions and diseases said to be alleviated form such symptoms, conditions and disease by the administration of the claimed compounds. The current state of the art for alleviating symptoms,

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conditions or diseases are symptom, condition or disease and drug specific. That is a particular drug can relieve specific symptom, condition or disease but no umbrella treatment for such enormous symptoms, conditions or diseases as in claim 37 was found. For any one compound being able to be used for all the conditions listed in claim 37 would be incredible.

It is not exactly clear what was the purpose for the applicants to recited tables 1 and 2 from the specification in the response. If the recitation is explaining that the in vitro and in vivo data in the specification support the scope that the compounds are operable in treating pain, then, no claim to such scope was offered. If the recitation is for supporting all the conditions and diseases of claim 37, then, nowhere in the specification or in the prior art that treating pain is automatically linked to treating such conditions as hearing loss, asthma, glaucoma etc. as recited in claim 37.

In addition, claim 37 is a "compound" claim. If the scope of compounds is the same as that of claim 1, then this is a essential duplicate of claim 1. If the scope of the compounds is whichever is active in one of the diseases, then, it lacks support from the specification which compound among the myriads has what activity and how a nexus has been established.

It is recommended that the duplicate claim 37 be canceled. A method of treating pain with the same scope as the compound claim, be presented for rejoinder.

4. The objection of claim 15 is maintained.

Reference recited on PTO-892 are for showing the state of the art.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie, Ph. D., can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Jun. 5, 2007



Celia Chang
Primary Examiner
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